SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	PAROXETINE TABLETS
Registration number	-
Synonyms	PAROXETINE 10MG TABLETS * PAROXETINE 20MG TABLETS * PAROXETINE 30MG TABLETS * AROXAT TABLETS * DEROXAT TABLETS * PAXIL TABLETS * PAROXAT TABLETS * PAROXETIN TABLETS * PAROXETINA TABLETS * AROPAX TABLETS * TAGONIS TABLETS * SEROXAT TABLETS * SEREUPIN TABLETS * PAROXETINE HYDROCHLORIDE HEMIHYDRATE, FORMULATED PRODUCT
Issue date	26-May-2018
Version number	21
Revision date	26-May-2018
Supersedes date	25-April-2017

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Medicinal Product. This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

Company name	GlaxoSmithKline UK
Address:	980 Great West Road Brentford, Middlesex TW8 9GS UK
Telephone:	+44-20-8047-5000 (General Inquiries)
Email:	msds@gsk.com
Website:	www.gsk.com

EMERGENCY CONTACTS

	CHEMTREC EMERGENCY NUMBERS
Telephone:	+(44)-870-8200418 (In country) +(1) 703 527 3887 (International) 24/7; multi-language response
Contract Number:	CCN9484
	VERISK 3E GLOBAL INCIDENT RESPONSE
Telephone:	+(44) 20 35147487 or 0 800 680 0425 (In country) +(1) 760 476 3961 (International) 24/7; multi-language response
Contract Number:	334878

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.3. Other hazards Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
CALCIUM PHOSPHATE, DIBASIC	80 - < 90	7757-93-9 231-826-1	-	-	
Classification:	Skin Irrit. 2;H315, Eye Irrit. 2;H319				
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	5 - < 10	110429-35-1 -	-	-	
Classification:	Acute Tox. 4;H302, Eye Dam. 1;H318, STOT SE 3;H335, Repr. 2;H361fd, STOT RE 1;H372, Aquatic Chronic 2;H411				
HYDROXYPROPYL METHYL CELLULOSE	1 - < 3	9004-65-3 -	-	-	
Classification:	-				
MAGNESIUM STEARATE	1 - < 3	557-04-0 209-150-3	-	-	
Classification:	-				
Titanium dioxide	< 1	13463-67-7 236-675-5	-	-	
Classification:	Carc. 2;H351				

Other components below reportable levels 1 - < 3

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.

4.2. Most important symptoms and effects, both acute and delayed The following adverse effects have been noted with therapeutic use of this material: nausea; diarrhoea; constipation; dry mouth; drowsiness; dizziness; weakness; insomnia; sexual dysfunction; tremor; palpitations.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

6.3. Methods and material for containment and cleaning up Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent product from entering drains. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

6.4. Reference to other sections For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Do not get this material in contact with eyes. Avoid prolonged exposure. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) Medicinal Product.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)	OHC	1	
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1	
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)	8 HR TWA	40 mcg/m3	Reproductive hazard
	OHC	3	Reproductive hazard

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no effect levels (DNELs)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

Exposure guidelines

8.2. Exposure controls

Appropriate engineering controls	General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166).
Skin protection	
- Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust).
Respiratory protection	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Environmental exposure controls

Hazard guidance and control recommendations	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.

Solubility(ies)

Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information

General information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	May be irritating to the skin.
Eye contact	Risk of serious damage to eyes.
Ingestion	May be harmful if swallowed.
Symptoms	The following adverse effects have been noted with therapeutic use of this material: nausea; diarrhoea; constipation; dry mouth; drowsiness; dizziness; weakness; insomnia; sexual dysfunction; tremor; palpitations.

11.1. Information on toxicological effects

Acute toxicity Risk of serious damage to eyes. May be harmful if swallowed.

Components	Species	Test results
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)		
Acute		
Dermal		
LD50	Rabbit	> 7940 mg/kg
Oral		
LD50	Rat	> 10 g/kg
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)		
Acute		
Oral		
LD50	Rat	374 mg/kg
Chronic		
Oral		
NOAEL	Monkey	3.5 mg/kg/day, 52 weeks

Components	Species	Test results
	Rat	5 mg/kg/day, 52 weeks
TD	Monkey	6 mg/kg/day, 52 weeks
	Rat	25 mg/kg/day, 52 weeks
Titanium dioxide (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose
		5 mg/m3, 24 months
Subacute		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

Titanium dioxide	0, Literature data Result: Non-irritant Species: Guinea pig 0, Literature data Result: Non-irritant Species: Human Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Acute dermal irritation; OECD 404, Primary Irritation Index: 0 Result: Non-irritating to intact skin Species: Rabbit Acute dermal irritation; OECD 404, Primary Irritation Index: 3 Result: Irritating to damaged skin. Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE	0

Serious eye damage/eye irritation Risk of serious damage to eyes.

Eye

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Acute ocular irritation; OECD 405, Kay and Calandra - Grade 8. Result: Very severe irritant Species: Rabbit

Eye

Titanium dioxide	OECD 405, Literature data Result: Mild irritant Species: Rabbit

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory sensitisation No studies have been conducted.

Skin sensitisation This product is not expected to cause skin sensitisation.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE	Result: negative Species: Guinea pig

Sensitisation

Titanium dioxide	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Maximisation assay (Magnusson and Kligman); OECD 406, 0 % Response rate. Result: negative Species: Guinea pig
Titanium dioxide	Patch test, Literature data Result: negative Species: Human

Germ cell mutagenicity

Mutagenicity

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Ames Assay, Screening assay Result: negative
Titanium dioxide	Ames, Literature data Result: negative
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Chromosomal Aberration Assay In Vitro Result: negative GreenScreen mammalian cell mutation assay Result: negative
Titanium dioxide	Micronucleus Assay in vitro, CHO cells, Literature data Result: negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Micronucleus Assay, GLP Result: negative Species: Mouse Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP Result: negative Mutation in Drosophila melanogaster Result: negative Sister Chromatid Exchange Result: negative
Titanium dioxide	Syrian Hamster Embryo (SHE) cell transformation assay Result: negative
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Unscheduled DNA Synthesis, in vivo - in vitro Result: negative Species: Rat
Titanium dioxide	WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: Positive

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure. Contains a material (Titanium dioxide) classified as a carcinogen by external agencies. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect.

Titanium dioxide	0.5 mg/m3, Literature data Result: negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months

Carcinogenicity

Titanium dioxide	25000 - 50000 ppm, Dietary study - Literature data. Result: negative Species: Rat 25000 - 50000 ppm, Dietary study Result: negative Species: Mouse 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Result: negative Species: Mouse Test Duration: 18 months Result: negative Species: Rat Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

Titanium dioxide (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

Reproductive toxicity Suspected of damaging fertility. Suspected of damaging the unborn child. Epidemiology studies have identified the ingredient paroxetine hydrochloride hemihydrate as a possible cause of developmental toxicity in humans.

Reproductivity

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	>= 50 mg/kg/day Embryo-foetal development Result: Maternal toxicity; adverse foetal effects Species: Rat 13 mg/kg/day Fertility, Female Result: Maternal toxicity; adverse effects on offspring. Species: Rat 13 mg/kg/day Fertility, Male Result: Parental toxicity, no adverse effects on fertility. Species: Rat 3 mg/kg/day Embryo-foetal development Result: Maternal NOAEL Species: Rabbit 4.3 mg/kg/day Fertility, Female Result: NOAEL Species: Rat 5 mg/kg/day Embryo-foetal development Result: NOAEL Species: Rat 6 mg/kg/day Embryofetal Development Result: Maternal toxicity; Foetal NOAEL Species: Rabbit Embryo-foetal development, Possible association with clinical use reported in epidemiology studies. Species: Human Organ: Cardiovascular malformations Fertility, Male, Possible association with clinical use reported in epidemiology studies. Result: Reversible effects on sperm quality. Species: Human

Specific target organ toxicity - single exposure May cause damage to organs.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Organ: Central nervous system.

Specific target organ toxicity - repeated exposure May cause damage to organs.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Epidemiology Organ: Bone; Testes (reversible).

Aspiration hazard Not likely, due to the form of the product.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

SECTION 12: Ecological information

12.1. Toxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test results
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
Acute			
Fish	EC50	Fish	> 100 mg/l, 96 hours
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	25 mg/l, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	2.5 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	0.49 mg/l, 48 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1.6 mg/l, 96 hours Static test, OECD 203
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	0.18 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8.2 mg/l, 15 minutes
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	0.5 mg/l, 7 days Static renewal test, EPA 2002
	NOEC	Water flea (Ceriodaphnia dubia)	0.25 mg/l, 7 days
Titanium dioxide (CAS 13463-67-7)			
Aquatic			
Fish	LC50	Mummichog (Fundulus heteroclitus)	> 1000 mg/l, 96 hours
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test

* Estimates for product may be based on additional component data not shown.

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 2.4 Hours Measured, Deionized Water

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 292 nm, pH 5-9

Hydrolysis

Half-life (Hydrolysis-neutral)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE > 1 years Measured, Deionized Water

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE 77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE 95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

HYDROXYPROPYL METHYL CELLULOSE -5

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 1.3

Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE 3.2 Estimated

MAGNESIUM STEARATE	> 9999 Estimated

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	2.94 Measured

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	0.8 Estimated

Mobility in general

Volatility

Henry's law

HYDROXYPROPYL METHYL CELLULOSE	0 atm m3/mol Estimated
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	0 atm m3/mol Calculated

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. - 14.6.: Not regulated as dangerous goods.

IATA

14.1. - 14.6.: Not regulated as dangerous goods.

IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. Pregnant women should not work with the product, if there is the least risk of exposure.
National regulations	Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any H-statements not written out in full under Sections 2 to 15	H302 Harmful if swallowed. H315 Causes skin irritation. H318 Causes serious eye damage. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H351 Suspected of causing cancer. H361fd Suspected of damaging fertility. Suspected of damaging the unborn child. H372 Causes damage to organs through prolonged or repeated exposure. H411 Toxic to aquatic life with long lasting effects.
Revision information	SECTION 2: Hazards identification: Hazard statements SECTION 2: Hazards identification: Supplemental label information Composition / Information on Ingredients: Ingredients SECTION 10: Stability and reactivity: 10.4. Conditions to avoid SECTION 11: Toxicological information: Carcinogenicity SECTION 11: Toxicological information: Reproductivity
Training information	Follow training instructions when handling this material.
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.